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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,858	10/06/2000	Peter Beetham	PM49317/272063	9880

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,858	BEETHAM ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 28-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 28-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SJD

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed on 16 June 2005.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 24 and 28-38 remain rejected and claims 39-41 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 March 2005. Applicant's arguments filed 6 June 2005 have been fully considered but they are not persuasive.

Applicants argue that the present specification makes its perfectly clear to one of ordinary skill in the art how to practice the presently claimed invention and that a mixed duplex oligonucleotide (MDON) is prepared that has homologous and heterologous regions of the targeted gene. Applicants argue that in reference to the Kmiec art the description of inventions in this area of technology are different than say the written description requirements for cDNA, which was the subject of *U. of C. vs. Eli Lilly* case and that the present claims are not directed to cDNA and can only be fairly described as set forth in the specification and pending claims, hence Applicants have described a

method to make mutations in microspores by the use of MDONS (page 4 of the Remarks). These arguments are not found to be persuasive. Applicants' argument that a description of a general method of making adequately describes the genus of products made is not persuasive. The instant claims encompass a composition comprising an MDON that is capable of introducing a mutation into any gene of a plant. The function of the MDON is intimately related to its structure. The instant claimed composition(s) requires knowledge, i.e. adequate description by Applicants or the art, of the target genomic sequence in order to make said composition(s). The structure of the MDON used requires such knowledge of the target genomic sequence, and the level of knowledge of the art at the time of the invention was not mature and those of skill in the art after Applicants' invention discovered that the use of MDONS did not predictably produce the desired mutation in a plant cell and thus could not infer function based on structure (see Kochevenko *et al* 2003 cited in the Office action mailed 19 November 2003). The nature of the method of making described in the instant application is such that the product made is indistinguishable from a product made by a different method, such as by natural or chemical mutation. As directed to claims 30-41, see *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from

its ostensible objects, that the patentee is required to distinguish his invention in his specification.

4. Claims 24 and 28-38 remain rejected and claims 39-41 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 March 2005. Applicant's arguments filed 6 June 2005 have been fully considered but they are not persuasive.

Applicants argue that gene repairs in and of itself was known in the art at the time of the present priority date the application of the gene repair technology to microspores does not make the presently claimed inventions "not routine" and unpredictable as far as the physical laboratory procedures are concerned. Applicants argue that the scope of the present claims is similar to the scope of the Kmiec '350 and Kmiec '181 patent claims in that they do not specify a specific gene or a specific oligonucleotide and that the Applicants are unaware of any reason to equate a "prophetic" example(s) with a "non-enabling" teaching (page 5 of the Remarks). The issue of enablement as directed to the Kmiec patents will not be discussed by the Examiner because each application is examined upon its own merits. These arguments are not found to be persuasive for the reasons given in the previous Office action. Making mutations in plant cells, encompassed by microspores, using MDONs was not

routine in the art at the time of Applicant's invention. Making said mutations using MDONs in a plant cell were not predictable at the time of Applicant's invention as outlined in the previous Office action. Applicant's guidance in the instant specification is prophetic and does not provide an enabling disclosure for the breadth of the claimed invention (pages 27-30 of the specification). See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

Claim Rejections - 35 USC § 102

5. Claims 30-38 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Swanson *et al* 1989 (Theoretical and Applied Genetics 78:525-530). This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 March 2005. Applicant's arguments filed 6 June 2005 have been fully considered but they are not persuasive.

Applicants argue that Swanson *et al* cannot be anticipatory because Swanson *et al* have no data confirming that the mutations made to the microspores were genomic

mutations to a specific gene responsible for imidazolinone resistance. Applicants argue that Swanson *et al* speculate that "genes" have been modified but there is no data confirming that fact and that non-genomic DNA is also present in plant cells that could also have been mutated instead of genomic DNA (page 5 of the Remarks). These arguments are not found to be persuasive. Sulfonylurea and imidazolinone resistance in *Brassica* sp. arises from a mutation in a gene encoding an acetolactate synthase enzyme, a genomic gene, not a plasmid gene. Given the evidence of Swanson *et al* the mutation of a genomic gene appears inherent in the disclosure of the prior art. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same, material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the Applicant to provide that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

6. Claims 24, 28, 29 and 30-36 remain rejected and claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (US Patent 5,731,181, filed 17 June 1996) in view of Fennell *et al* (1992, Plant Cell Reports 11:567-570) and Hawkes *et al* (WO 98/54330, published 3 December 1998, priority date 28 May 1997). This rejection is repeated for the reason of record as set forth in the last Office action

mailed 16 March 2005. Applicant's arguments filed 6 June 2005 have been fully considered but they are not persuasive.

Applicants argue that Hawkes *et al* do not teach or motivate anyone to introduce an MDON into a plant haploid cell in those general teaching terms, rather Hawkes *et al* only discloses introduction of MDONS into pollen cells. Applicants argue that they have distinguished the differences between pollen and microspore cells and that construction of the teachings of Hawkes *et al* is hindsight reconstruction based on the present disclosure after the fact. Applicants argue that the Fennell *et al* reference relates to transformation and not gene repair, transformation employs much larger nucleotides with differences in properties discussed in prior responses (page 6 of he Remarks). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The teachings of Hawkes *et al* demonstrates that one of ordinary skill in the art at the time of Applicant's invention would have been motivated to introduce an MDON into a haploid plant cell, and Fennell *et al* teach that a plant microspore is a preferred species of a haploid plant cells.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

8. Applicant remains advised that should claim 31 be found allowable, claim 35 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Applicants defer addressing this issue in the response filed on 16 June 2005 at page 6. The objection as directed to claims 30 and 34 is withdrawn because they encompass different scopes.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

David H. Kruse, Ph.D.
6 September 2005

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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